

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Appl. Serial No.:** 10/559,595

**Confirmation No.:** 2750

**Inventors:** Ong et al.

**TC/A.U.:** 1654

**Filing Date:** November 30, 2005

**Examiner:** Harle, Jennifer I

**Title:** *Novel Methods and Compositions for Enhanced Transmucosal Delivery of Peptides and Proteins*

**Reply to Requirement for Restriction**

Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

Sir:

This is in response to the requirement for restriction mailed November 20, 2007. In response the Applicant hereby elects Group I, claims 1-25, with traverse.

Applicant was also required to elect a species in the following categories, and elects as follows:

For the buffer, Applicant elects glutamic acid, claims 1-25 are readable thereon.

For the cationic polyamino acid, Applicant elects poly-arginine, claims 1-25 are readable thereon.

For the tonicifying agent, Applicant elects sodium chloride, claims 1-25 are readable thereon.

For the viscosity-increasing agent, Applicant elects hydroxypropyl methylcellulose, claims 1-25 are readable thereon.

For the bioadhesive agent, Applicant elects carbomer, claims 1-25 are readable thereon.

For the preservative, Applicant elects methyl paraben, claims 1-25 are readable thereon.

For the peptide, Applicants elect exendin-4 (SEQ ID NO. 2), with traverse. Claims 1-11, 17-25 are readable thereon.

The restriction requires election of a single peptide as the invention, alleging that "each peptide is assumed to be a patentably distinct invention, in the absence of specific, substantial, and credible evidence to the contrary." (Restriction Requirement mailed 11/20/2007, p. 4). In a telephone message left on December 20, 2007 for attorney Richard San Pietro, Examiner Harle stated that the requirement was made in view of MPEP § 1850, sub-part XIII. However, this passage relates to cases before the International Search Authority with respect to nucleotide sequences where the claimed subject matter lacks unity (i.e., does not involve "one or more of the same or corresponding special technical features,"), thus allowing an invitation to pay additional fees to maintain claims in the same application before the International Search Authority. This passage does not justify a requirement of electing a single sequence as the invention at the National Stage. Furthermore, the passage only relates to nucleotide sequences, not to the presently claimed amino acid sequences.

Thus, Applicant submits the requirement for election of invention here is improper. A more applicable text is found at MPEP § 1893.03(d), which states "[w]hen making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group." Yet Applicant has been provided with no such listing or explanation.

While Applicants are otherwise receptive to a reasonable grouping of claims or sequences as the invention, a requirement to limit the application to a single sequence is improper and finds

no basis in the patent rules for purposes of restriction, particularly in view of the very high amount of sequence homology between claimed sequences. Thus, reconsideration of the restriction is respectfully requested and that a reasonable grouping of claims be provided.

**Closing**

No fees are believed due with this response that are not otherwise provided for herein. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535. Additionally, the Commissioner is hereby authorized to charge any underpayment or credit overpayment of fees during the pendency of this application to Applicant's Deposit Account No. 010535.

The Examiner or other PTO personnel are also invited to contact the undersigned in the event that a telephone call can facilitate or speed prosecution in some way.

Respectfully submitted,

Dated: Dec. 20, 2007

By: *Richard S. Pietro*  
Richard San Pietro  
Registration No. 45,071

AMYLIN PHARMACEUTICALS, INC.  
9360 Towne Centre Drive  
San Diego, CA 92121  
Telephone: 858-754-4981  
Facsimile: 858-552-1936